escribing Information Presentation: White, capsule-shaped tablets embossed MODALIM on one side with a breakline on the other, each containing 100mg ciprofibrate. **Uses:** For the treatment of primary hyperlipidaemia resistant to appropriate dietary management, including percholesterolaemia, hypertriglyceridaemia and combined hyperlipidaemia. In the Fredrickson classification, this includes types IIa, IIb, III and IV. **Dosage: Adults:** Initially one tablet (100mg ciprofibrate) per day is recommended with subsequent adjustment according to erapeutic response. The maximum dose should not exceed 2 tablets (200mg ciprofibrate) per day which may be taken as a single dose. **Elderly patients:** As for adults but see precautions and warnings. **Use in impaired renal function:** In moderate renal impairment it is commended that dosage be reduced to one tablet every other day. Patients should be carefully monitored. MODALIM should not be used in severe renal impairment. **Use in children:** Not recommended since safety and efficacy in children have not been established. **ntra-indications:** Severe hepatic impairment, severe renal impairment, pregnancy and lactation. **Use in pregnancy and lactation:** There is no evidence that ciprofibrate is teratogenic, but there were signs of toxicity at high doses in teratogenicity tests in animals, and ciprofibrate is been shown to be excreted in breast milk in rats. In the absence of data on its use in human pregnancy or lactation, MODALIM is contraindicated during pregnancy and in nursing mothers. **Precautions:** Use with caution in patients with impaired renal or hepatic function. normal liver function tests have been observed occasionally. Periodic liver function tests are recommended. MODALIM treatment should be halted if liver enzyme abnormalities persist. If, after several months therapy, serum lipid concentrations are not satisfactorily ntrolled, additional or different therapeutic measures should be considered. **Interactions:** Ciprofibrate is highly protein bound and therefore likely to displace other drugs from plasma protein binding sites. MODALIM has been shown to potentiate the effect of warfarin dicating that concomitant oral anticoagulant therapy should be given at reduced dosage and adjusted according to prothrombin time. Although there are no specific data, it is likely that ciprofibrate will also potentiate the action of oral hypoglycaemic agents and its action ay be affected by oral contraceptives. There is evidence that the concomitant use of fibric acid derivatives with HMG CoA reductase inhibitors may predispose patients to myopathy. **Side effects:** There have been occasional reports of headache, vertigo, rashes and gastrointestinal mptoms including nausea, vomiting, diarrhoea and dyspepsia. Generally these side effects were mild to moderate in nature and occurred early on, becoming less frequent as treatment progressed. As with other drugs of this class, ow incidence of myalgia, impotence and hair loss has been reported. Dizziness, drowsiness or tiredness have only rarely been reported in association with MODALIM. It is therefore unlikely to affect ability to drive or to use machinery. **gal Category:** POM. **NHS Price:** £13.38 per pack of 28 tablets. PL11723/0050. MODALIM is a registered trade mark. **Date of preparation:** 1/94. **References:** 1. Assmann G & Schulte H. *Am J Cardiol* 1999; **70** (7): -3-737. 2. Farnier M *et al. J Drug Dev* 1999; **5** (1): 13-21. Further information is available on request from: Sanofi Winthrop Limited, One Onslow Street, Guildford, Surrey GU1 4YS.

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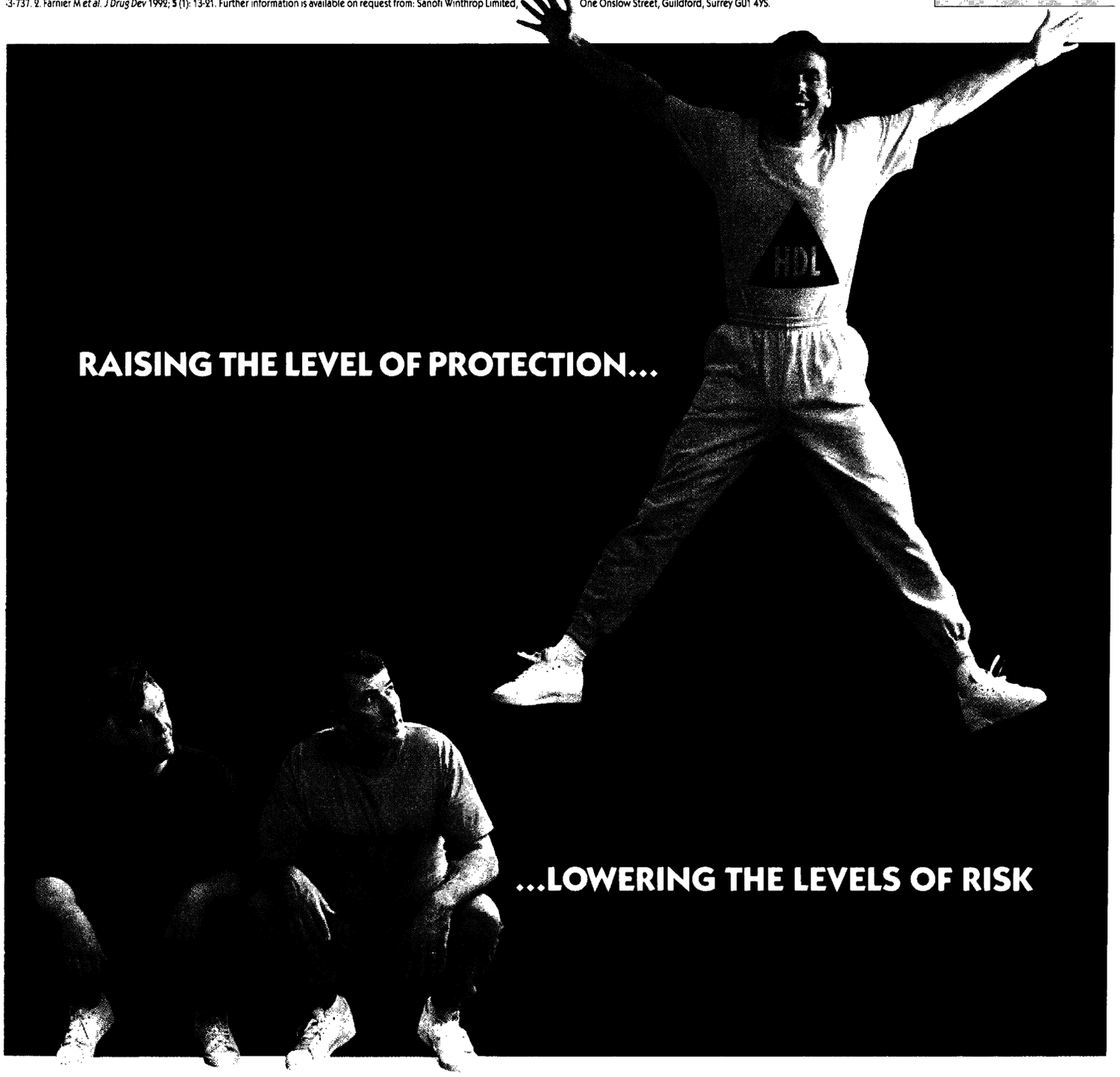

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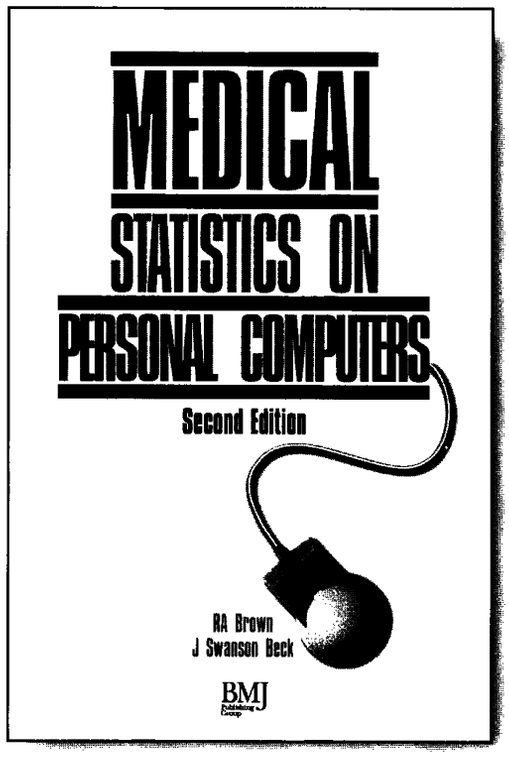

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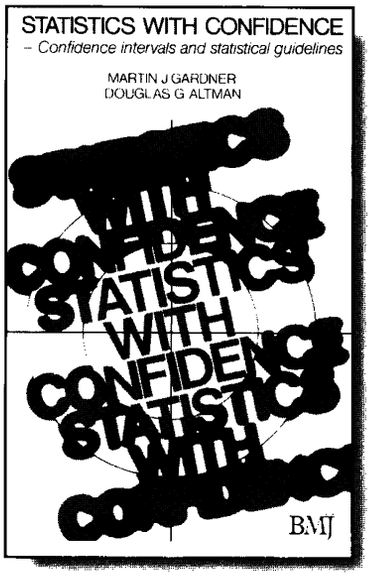

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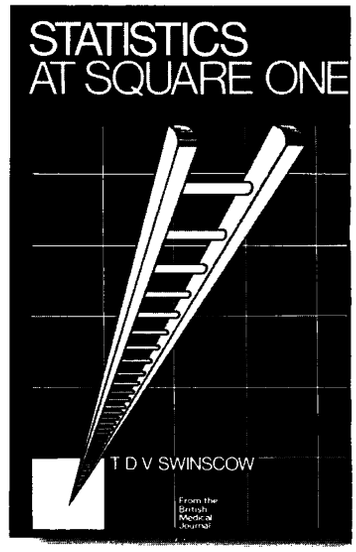

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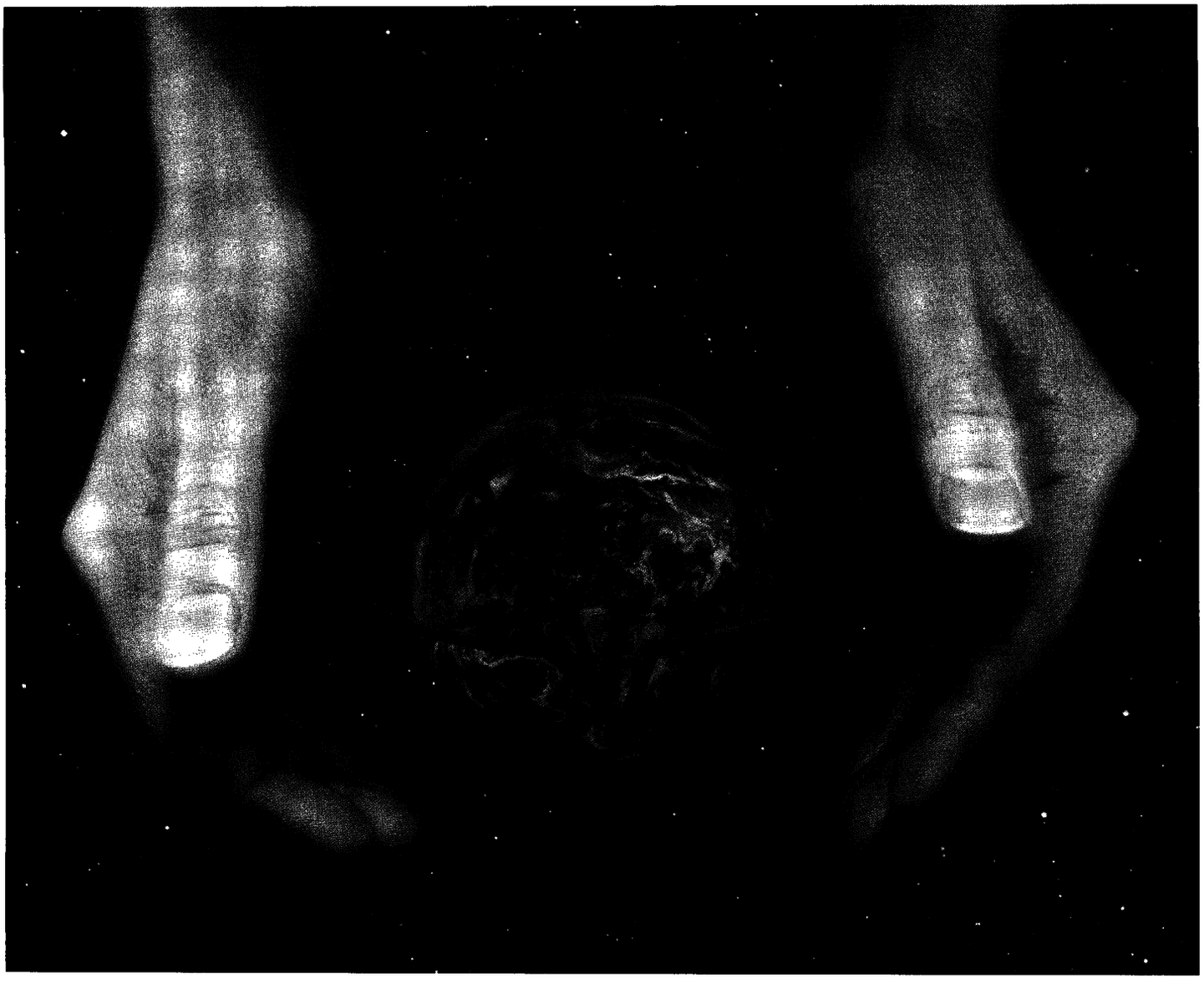

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)SAGE AND ADMINISTRATION *Hypertension:* Initially, 5 mg once ly, reduce starting dose to 2.5 mg if over 65 years, on diuretics or renally aired. Adjust dose according to response; maintenance usually 10-20 once daily. Maximum dose 40 mg daily. Diuretic-treated patients – if ssible stop diuretic two to three days before starting 'Innovace'. Resume retic later if required. *Heart failure (adjunctive therapy):* Initially, 2.5 daily under medical supervision (hospital initiation for severe heart ure; hospital initiation for high-risk patients is recommended), increasing he usual maintenance dose of 20 mg daily according to tolerability. This age schedule has been shown to improve survival. *Impaired renal ction:* May require a lower maintenance dose. 'Innovace' is dialysable.

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:ECAUTIONS Assess renal function prior to therapy with 'Innovace' l during therapy where appropriate. Renal insufficiency: possibility of hypotension especially in ischaemic heart disease or cerebrovascular disease or in volume-depleted patients; surgery/anaesthesia. Combination with antihypertensives may increase hypotensive effect. In some patients with bilateral renal artery stenosis increased blood urea and creatinine has been seen, especially in patients treated with diuretics and/or those with renal insufficiency. Minimises thiazide-induced hypokalaemia and hyperuricaemia. Potassium supplements, potassium-sparing diuretics, and potassium-containing salt substitutes are not recommended.

Possible reduced response in Afro-Caribbean patients. Use with caution in breast-feeding mothers. Do not use in aortic stenosis, or outflow tract obstruction. Monitor serum levels of lithium, if lithium salts are given. ACE inhibitors should be avoided in patients dialysed with high-flux membranes.

SIDE EFFECTS Side effects include: dizziness, headache. Others include fatigue, asthenia, hypotension, orthostatic hypotension, syncope, nausea, diarrhoea, muscle cramps, rash, cough. Less commonly, angioneurotic oedema, other hypersensitivity reactions, renal failure; symptomatic hypotension (especially if volume-depleted); severe hypotension (more likely if severe heart failure); hyperkalaemia; hyponatraemia, increases i liver enzymes and serum bilirubin (usually reversible on discontinuation ('Innovace'); paraesthesiae; impotence. A complex of symptoms has bee reported which may include fever, serositis, vasculitis, myalgi arthralgia/arthritis, a positive ANA, elevated ESR, eosinophilia an leucocytosis. Rash, photosensitivity or other dermatological manifestatior may occur.

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References: 1. Jones, R. I., *et al., Amer. J. Cardiol.*, 1985, *55*, 153 **2.** Yusuf, S., *et al., Lancet*, 1992, *340*, 1173. **3.** The SOLVD Investigator *New Engl. J. Med.*, 1992, *327*, 685. **4.** The CONSENSUS Trial Study Group, *New Engl. J. Med.*, 1987, *316*, 1429. **5.** Data on file, Merck Sharp & Dohme Limited.

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IMD 953

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